CERTIFICATION OF ADMINISTRATIVE RULES
FILED WITH THE SECRETARY OF STATE
CATHY COX

(Pursuant to OCGA §§ 50-13-3, 50-13-4, and 50-13-6.)

I do hereby certify that the attached is a correct copy of revised Rules 290-9-8-.03, 290-9-8-.06 and 290-9-8-.33 as promulgated and adopted on the 16th day of August, 2006.

GEORGIA DEPARTMENT OF HUMAN RESOURCES

Filed August 21, 2006.

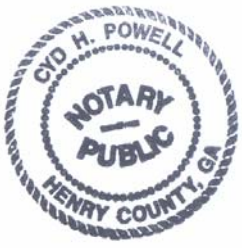
The attached Rules 290-9-8-.03, 290-9-8-.06 and 290-9-8-.33 within Rules Chapter 290-9-8 entitled "Licensure of Clinical Laboratories," are hereby adopted in lieu of the current Rules of the same numbers and titles.

Statutory Authority: OCGA § 31-22-1 et seq..

B. J. Walker
Commissioner

Sworn to and subscribed before me
this 21st day of August, 2006.

Cyd H. Powell
Notary Public, Henry County, Georgia
My commission expires February 1, 2008



RULES
OF
DEPARTMENT OF HUMAN RESOURCES
OFFICE OF REGULATORY SERVICES

CHAPTER 290-9-8
LICENSURE OF CLINICAL LABORATORIES

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290-9-8-.03 Definitions Amended. Unless a different meaning is required by the context, the following terms as used in these rules and regulations shall have the meaning hereinafter respectively ascribed to them:

(a) **Analyte** means a substance or constituent for which the laboratory conducts testing;

(b) **Board** means the Board of Human Resources of the State of Georgia;

(c) **Clinical Laboratory** means a facility for the biological, microbiological, serological, immunological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from or produced by the human body for the diagnosis of, recommendation of, treatment of, or for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of human beings, the term "Clinical Laboratory" shall include

specimen collection stations and shall include blood banks which provide through their ownership or operation a system for the collection, processing, or storage of human blood and its components as well as tissue banks which procure, store, or process human or animal tissues designed to be used for medical purposes in human beings;

(d**) CLIA-exempt state** means a state where the Centers for Medicare & Medicaid Services (CMS) has determined that the state has enacted laws/rules relating to laboratory requirements that are equal to or more stringent than CLIA requirements. All laboratories subject to state licensure will be considered as "CLIA exempt" where the state has been determined to be CLIA exempt;

(e) **Commissioner** means the Commissioner of the Department of Human Resources of the State of Georgia;

(f) **Department** means the Georgia Department of Human Resources;

(g) **Director** means a person who is responsible for the administration of the technical and scientific operation of a clinical laboratory, including supervision of procedures for testing and the reporting of results;

(h) **Evaluation Program** means a state-conducted or state-approved proficiency testing program;

(i) **Facility** means a building, structure, institution, place, or entity, which may be fixed or mobile;

(j) **Laboratory Advisory Council** means the Clinical Laboratory, Blood Bank and Tissue Bank Committee authorized and required by law and appointed by the Board;

(k) **Laboratory Test** means any examination and/or manipulation performed on a specimen produced by the human body, by procedures such as phlebotomy or blood diverted from a normal or life-sustaining circulatory path, or in vivo testing of body fluids for the purpose of diagnosis, treatment, monitoring or the assessment of the health of human beings;

(l) **Limited specialty laboratory or limited laboratory specialty** means a clinical laboratory, or part of a clinical laboratory, in which testing is restricted (limited) to a designated category or subcategory, including but not necessarily limited to the following examples: cytology, histology, tissue banking, special chemistries (radio bioassay, blood gases, toxicology, etc.), cytogenetics and histocompatibility;

(m) **Other Personnel** means non-technical personnel who may be employed in the laboratory such as aides, clerks, etc. These persons may assist laboratory technical staff, but do not themselves qualify as technical staff or perform tests;

(n) **Person** means any individual, firm, partnership, association, corporation, the State or any municipality or other subdivision thereof, or any other entity whether organized for profit or not;

(o) **Pertinent Laboratory Experience** means full time or equivalent work in a clinical laboratory, directing, supervising or performing tests in all categories, or, when limited to laboratory specialty(ies), work is restricted to that category/subcategory;

(p) **Plan of Correction means** a written plan submitted by the laboratory director, owner, or other controlling authority, for approval by the Department. The plan shall identify the existing noncompliance of the laboratory and the proposed procedures, methods, means and reasonable period of time needed to correct the noncompliance;

(q) **Point of Care Technician** means a medical professional person subject to these rules, who has received special training in point of care testing as defined by these rules. Medical professional staff authorized to perform point of care testing are limited to registered professional nurses, certified nurse practitioners, licensed practical nurses, certified respiratory care professionals, physician assistants, certified paramedics, certified emergency medical technicians, perfusionists, laboratory technologists, laboratory technicians and certified cardiovascular technologists, radiologic technologists certified by a professional credentialing organization approved by the Department, and phlebotomists, certified by a professional credentialing organization approved by the Department;

(r) **Point of Care Testing** means testing performed in the immediate proximity of the patient. All point of care testing must be approved by and under the supervision of a Georgia-licensed laboratory, unless the test site meets the requirements for exemption. All such point of care testing shall be approved only in the specialties for which the laboratory holds a license. Testing shall be limited to procedures which meet all current Georgia rules for quality control, quality assurance and Point of Care Testing personnel requirements. Point of Care Testing is exclusive of screening and monitoring tests;

(s) **Quality Assurance** means a comprehensive process used by the laboratory to prevent and control errors that may occur at any interval from the time a test is ordered until it is reported and charted;

(t) **Quality Control Program** means those quality control requirements established for clinical laboratories as provided in applicable federal law and regulations and in Georgia law and regulations;

(u) **Screening and Monitoring Tests**. Screening tests mean those simple laboratory tests, approved by the Board as screening tests, used to aid in the detection of previously undiagnosed conditions. Monitoring tests mean those simple laboratory tests, approved by the Board as monitoring tests, with performance characteristics (accuracy and precision) that allow the tests to be used for evaluation of the status of previously diagnosed conditions and/or for evaluation of response to medical management;

(v) **Specimen Collection Station** means a place or entity, without regard to location, that either collects specimens directly from patients or brings specimens together after collection for the purpose of forwarding them either intrastate or interstate to a licensed/certified clinical laboratory for examination;

(w) **Specimen Collector and/or Phlebotomist** means any person who has been trained in procedures requiring understanding and skills in the procurement of specimens for clinical laboratory analysis in Clinical Chemistry, Hematology, Immunohematology, Microbiology, and Immunology/Serology and who works under the general supervision of the laboratory director, supervisor or technologist;

(x) **Supervisor** means an assistant to the director and a person with special scientific skills, who, under the general supervision of a clinical laboratory director, supervises technical personnel;

(y) **Technician** means any person other than the clinical laboratory director, supervisor, technologist, or trainee who functions under the supervision of a clinical laboratory director, supervisor, or technologist and performs only those clinical laboratory procedures which require limited skill and responsibility and a minimal exercise of independent judgment as described in 290-9-8-.06(5)(a). The degree of supervision by the clinical

laboratory director, supervisor, or technologist of a technician shall be determined by the director, supervisor, or technologist based on:

1. The complexity of the procedure to be performed;

2. The training and capability of the technician; and

3. The demonstrated competence of the technician in the procedure being performed;

(z) **Technologist** means a person who performs clinical laboratory procedures which require the exercise of independent judgment and responsibility, with minimal supervision by the director or supervisor, in only those specialties or subspecialties in which they are qualified by education, training, experience, and certification.

(aa) **Trainee** means a person who is enrolled in an accredited training program or who, in a limited laboratory specialty(ies) for which there is no accredited training program available, trains under the supervision of a director, supervisor, or technologist qualified in the specialty(ies), but does not report actual patient test results without prior supervisory approval.

Authority O.C.G.A. Sec. 31-22-1 et seq.

290-9-8-.06 Laboratory Personnel Requirements, Personnel Qualifications and Personnel Records.

(1) **Laboratory Personnel Requirements**:

(a) **General**. The laboratory shall perform tests in only those categories, subcategories or procedures for which it is licensed and for which there is either a director, supervisor, or technologist having minimum qualifications as outlined for Clinical Laboratory

Technologists in Rule 290-9-8-.06(4). (Special personnel requirements for donor screening and plasmapheresis and whole blood donor centers are outlined in Rule 290-9-8-.28). In addition, the following criteria shall be minimum personnel qualifications for the supervision of the categories and subcategories below:

1. Clinical Chemistry, Hematology, Immunohematology, Microbiology, Clinical Immunology and Serology: Supervisory requirements for these categories are those requirements for Clinical Laboratory Supervisor, outlined in Rule 290-9-8-.06(3).

2. Exfoliative Cytology. For the purpose of these rules, exfoliative cytology is defined as that part of laboratory science dealing with the examination of cells obtained from human body fluids, surfaces, tissues, and other sources. This service must be provided by either a licensed physician who is certified or eligible for certification in anatomic pathology or cytopathology by the American Board of Pathology or the American Osteopathic Board of Pathology or by applicants who have a doctoral degree and whose special field is cytology. Unless the physician/Ph.D. also serves as cytology general supervisor, the supervisor must meet the minimum qualifications outlined in Rule 290-9-8-.06(3)(b)5 or current federal regulations of §353 of the Public Health Service Act and Title 42 U.S.C. 263a, whichever is more stringent.

3. Anatomic Pathology. For the purpose of these rules, anatomic pathology is defined as the examination and diagnosis of human tissues whether removed during life or after death. It deals with the morphologic study of normal or abnormal structure of tissues. For the purpose of these rules, this definition includes performance of all autopsies including medical-legal, and forensic autopsies. The laboratory director, if not so qualified, shall engage the services of a licensed physician who is certified or eligible for certification in an anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology.

4. Oral Pathology. For the purpose of these rules, oral pathology is defined as a branch of anatomic pathology (see (a) 3. above). The laboratory director, if not qualified in oral pathology, shall engage the services of a licensed physician who is certified or eligible for certification in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or those of a dentist, licensed in the State of Georgia, who is certified or eligible for certification by the American Board of Oral Pathology.

5. Radiobioassay. For the purposes of these rules, radiobioassay is defined as the diagnostic in vivo study involving administration of radioactive materials to a human subject (with the exclusion of organ scanning). Laboratories performing tests in radiobioassay must have a director or supervisor who is a physician working in Georgia in the field of radiobioassay at the time of the adoption of these rules and regulations or is qualified and trained in nuclear medicine or radioisotopic pathology and/or is certified or eligible for certification by the American Board of Nuclear Medicine or the subspecialty of radioisotopic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology. If not so qualified, the laboratory must engage the services of one so qualified:

(i) In vitro studies of organs, tissues, or fluids, using radioactive materials are considered in the licensed category of Clinical Chemistry (special) and may be handled by those appropriately qualified in this area.

(ii) For both in vivo and in vitro studies, all users of radioactive material must comply with Georgia "Rules and Regulations for Radioactive Material", Chapter 290-5-23.

6. Qualifications for test areas not included in above general categories
may be established as Department policy.

(b) **Directors**. Each licensed laboratory shall be under the direction of a licensed laboratory director whose responsibilities and qualifications are outlined in Rule 290-9-8-.06(2). The director may delegate Point of Care Testing oversight to qualified laboratory supervisors; however, such delegation must be in writing. In addition, delegation of authority does not relieve director of responsibilities as outlined in these regulations regarding Point of Care Testing.

(c) **Supervisors.** With the exception of a laboratory in which the director also qualifies and serves as supervisor, each laboratory shall have one or more supervisors who serve as assistants to the laboratory director and whose responsibilities are outlined in Rule 290-9-8-.06(3). Such personnel must spend an adequate amount of time in the laboratory to supervise the performance of the work in the laboratory and must be readily available at other times for on-site or telephone consultation.

(d) **Technologists and Technicians**. Each laboratory shall engage the services of a sufficient number of clinical laboratory technologists, and/or clinical laboratory technicians to meet the workload demands including prompt performance, reporting and record-keeping of test results, quality control and proficiency testing.

(e) **Point of Care Technicians.** Each point of care testing site subject to state licensure shall utilize medical professional staff, as defined in these rules to perform such testing.

(f) **Specimen Collectors and Phlebotomists.** A laboratory may employ specimen collectors and/or phlebotomists whose responsibilities are outlined in Rule 290-9-8-.06(7).

(g) **Other Personnel.** No person may perform laboratory tests within a licensed laboratory unless they qualify as a trainee,

technician, technologist, supervisor, or director as defined in these rules. Other personnel may be employed in the laboratory such as aides, clerks, etc. These persons may assist the laboratory technical staff, but do not themselves qualify as technical staff, perform patient testing or operate clinical analyzers.

(h) **Personnel Records:**

1. Personnel records shall be kept current. They shall include a complete resume of each employee's training, experience, duties, competency evaluation and date or dates of employment. Personnel forms shall be submitted to the Department in a timely manner.

2. The laboratory is responsible for maintaining written documentation (in the personnel file of each employee performing testing) which demonstrates that the employee meets the personnel qualifications as set forth in these rules.

(2) **Licensed Laboratory Directors.**

(a) Responsibilities and general requirements:

1. Each licensed clinical laboratory shall be under the direction of a licensed laboratory director who is responsible for the operation of the laboratory at all times, who must spend an adequate amount of time in the laboratory to administer the technical and scientific operation of the laboratory, is responsible for the proper performance and reporting of laboratory findings, and is responsible for adequate staffing by qualified laboratory personnel, their in-service training and work assignment.

(i) There must be documentation completed by the laboratory director or supervisor, of competency to perform testing by an individual initially before patient testing is performed and not less than annually, thereafter, unless test methods or instruments

change, in which case the director or supervisor is responsible for completing a new competency validation on the individual(s) before test results can be reported. Competency is to be measured against an established performance standard as defined by the laboratory director. Methods for validation of competency for each procedure must include:

(I) Direct observation of test performance through the testing of previously analyzed specimens and internal blind samples or external proficiency testing samples previously run and recorded. Testing samples may not be labeled as competency evaluation material, but must be treated as patient samples for routine processing;

(II) Review of test results from tests performed as a part of the competency assessment;

(III) Assessment of response to problems or situations related to the procedure;

(IV) Review of documentation of critical incidents related to the individual's performance of the procedure;

(V) Response to written or oral questions related to the procedures and, if applicable to the individual's responsibilities,

(VI) Assessment of the performance of calibration, and review of records pertaining to quality control and instrument maintenance.

(ii) The laboratory director may delegate the responsibility for competency assessment to other directors or supervisors in the laboratory meeting the qualifications described in 290-9-8-.06(2) and 290-9-8-.06(3).

(iii) The licensed laboratory director shall ensure that no individual performs any laboratory procedure independently

without first having demonstrated competency for the procedure as described above in 290-9-8-.06(2)(a)1(i).

(iv) When a director will be continuously absent for more than four weeks, arrangements must be made for a qualified substitute licensed director.

2. In addition to responsibilities outlined at 290-9-8-.06(8)(a) and (b) of these rules, the director is responsible for ensuring that all testing is instituted and conducted in a manner that complies with all applicable rules. The director, in consultation with appropriate medical staff, shall prepare an internal needs assessment for point of care testing which shall include evaluation of patient benefits and criteria for establishing the necessity of such testing. The assessment shall also include an evaluation of proposed methodologies for tests to be performed. The director is responsible for terminating testing in cases where there is consistent non-compliance with applicable rules or substandard performance.

3. There must be a written plan of action for how patient testing and reporting is handled when either laboratory or point of care testing fails. The director must ensure that, when recommended by the manufacturer, all screening tests performed must have confirmatory tests performed in a timely manner. The director must also ensure that the laboratory is enrolled and successfully participates in an approved proficiency testing program and that each Point of Care Testing area either enroll and successfully participate in an approved proficiency testing program *or* successfully participate in an approved program subscribed to by the responsible laboratory. Point of Care Testing methods, analyzers, or test areas must be challenged the number of times a year as is consistent with the requirement for clinical laboratories under state and/or current federal regulations. The director may delegate his or her authority, to assure that all applicable state

regulations are met, to a supervisor that is qualified as defined in these rules and regulations.

4. Each licensed clinical laboratory must be served by a licensed clinical laboratory director, (permitted to direct no more than three clinical laboratories at a given time), on a full time or regular part-time basis. However, no licensed clinical director (Restricted) shall be permitted to direct more than one clinical laboratory at a given time.

(b) Qualifications:

1. Each licensed clinical laboratory in Georgia shall be directed by a licensed clinical laboratory director who qualifies under either (i), (ii), (iii), (iv), or (v) below, and whose practice is to be restricted according to the subparagraph under which he/she qualifies.

(i) **Licensed Clinical Laboratory Director.** A licensed clinical laboratory director must hold a license to practice medicine and surgery pursuant to Chapter 34 of Title 43 of the Official Code of Georgia Annotated, or a Georgia license to practice dentistry, or hold an earned doctoral degree in biology, microbiology, chemistry or related fields, and must either be certified or eligible for certification by one of the following:

(I) The American Board of Pathology or the American Board of Osteopathic Pathology in Clinical and/or Anatomic Pathology;

(II) The American Board of Oral Pathology;

(III) The American Board of Medical Microbiology;

(IV) The American Board of Clinical Chemistry;

(V) The American Board of Bioanalysists [Clinical Laboratory Director (CLD) and/or Bioanalyst Clinical Laboratory Director (BCLD)]; or

(VI) The American Board of Medical Laboratory Immunology; or

(VII) Qualified by other combinations of pertinent laboratory training and experience, in one or more of limited laboratory specialties, which are acceptable to the Department:

(ii) **Licensed Clinical Laboratory Director (Restricted**). In recognition that certain laboratories, due to varying circumstances, have difficulty providing a laboratory director qualified under the requirements above, the clinical laboratory director's license (restricted) is authorized for issuance to new applicants who are physicians or possess an earned doctoral degree and who are qualified as laboratory supervisors under Rule 290-9-8-.06(3)(b)1. or (b)2., and who meet the following requirements:

(I) The person will serve as director of only one laboratory at a given time;

(II) The served laboratory employs not more than ten full-time technical employees (supervisors, technologists, and technicians) or equivalent number of part-time technical employees; and

(III) The laboratory must also employ a qualified full-time or regular part-time clinical laboratory supervisor or pathologist.

(iii) **Licensed Clinical Laboratory Director (Plasmapheresis and/or Whole Blood Donor Centers).** The director of a plasmapheresis and/or whole blood donor center shall be a physician licensed in Georgia, who is qualified by training and/or experience in blood banking and/or plasmapheresis procedures and who shall be responsible for the medical, technical and clerical

services, including special services such as phlebotomy for autologous transfusion, and special pheresis technique.

(iv) **Licensed Clinical Laboratory Director (Specimen Collection Station).** Each specimen collection station which is not a part of a parent clinical laboratory that is licensed by the State of Georgia must have a licensed clinical laboratory director. The director of a Specimen Collection Station shall be a person who is licensed to practice medicine in Georgia, or who holds an earned doctoral degree in biology, microbiology, chemistry or a related field and have pertinent clinical laboratory experience related to specimen collection.

(v) A person, who at the time of adoption of these regulations holds a current Georgia license as a clinical laboratory director, may renew the license and continue to function with same or similar duties and responsibilities upon application and payment of license fee. Persons who qualify under this provision but who are inactive for two (2) consecutive years must meet current requirements. Provided, further, that individuals and laboratories so concerned must meet all other standards of performance required by law and accompanying rules and regulations.

2. In addition to the directorship of the clinical laboratory, the director may participate in actual laboratory work only in those areas in which qualified by training and experience. For those categories in which the director is not qualified, a supervisor must be employed who is qualified in accordance with Rule 290-9-8-.06(3) to perform and/or supervise those procedures independently.

3. The person serving as a hospital laboratory director must be a member of the hospital medical staff.

(3) **Laboratory Supervisor**.

(a) **Responsibilities and general requirements.** With the exception of a laboratory in which the director also serves as supervisor, each laboratory must have an adequate number of qualified personnel who are assistants to the director, and who, under his/her general direction may function as supervisors, depending upon the size of the laboratory and diversity of the laboratory testing. A supervisor must be available for two-way communication within 30 minutes during all hours of operation, for the purpose of supervising technical personnel. For Point of Care Testing areas, the responsible supervisor must be qualified at a minimum under subparagraph (3)(b)4 of this rule. In addition, the supervisor of the testing area must be available for two-way communication within 30 minutes during all hours of operation. The supervisor is responsible for developing a quality control and quality assurance program for each test area that is equal to or more stringent than current federal and applicable state requirements. No Point of Care Testing area may be operated without a qualified supervisor.

(b) **Qualifications.** A supervisor shall meet one of the following minimum requirements:

1. Hold a license to practice medicine and surgery pursuant to Chapter 34 of Title 43 of the Official Code of Georgia Annotated and have at least two years of pertinent laboratory experience; or

2. Hold a doctoral degree from an accredited institution with a chemical, physical, or biological science as the major subject and have at least two years of pertinent laboratory experience; or

3. Hold a master's degree from an accredited institution with a major in one of the chemical, physical or biological sciences, allied health science or laboratory management, and have at least three years of pertinent laboratory experience as a technologist as outlined in Rule 290-9-8-.06(4)(b) of these rules and regulations; or

4. Qualify as a clinical laboratory technologist under Rules 290-9-8-.06(4)(b)1, 2, 3 or 4 and have at least four years of pertinent laboratory experience as a technologist as outlined in Rule 290-9-8-.06(4)(b); or

5. In the limited specialty laboratory or limited laboratory specialty(ies), the supervisor must meet one of the above conditions or, if restricted to the category or subcategory, must meet one of the following:

(i) Hold a master's degree with a major in a chemical, physical, or biological science, allied health science, or laboratory management; be a graduate of an accredited program in the specialty and have at least two years pertinent laboratory experience in the specialty as technologist; or

(ii) Hold a bachelor's degree in the specialty; or a degree with a major in chemical, physical, or biological sciences and be a graduate of a program in the specialty accredited by an agency accepted by the Department, or have one year of training in a clinical laboratory environment; and have at least three years of pertinent laboratory experience in the specialty as a technologist; or

(iii) Qualify as a technologist under Rule 290-9-8-.06(4)(b)6.(i) and have at least four years of pertinent laboratory experience in the specialty as a technologist.

(iv) A cytology supervisor must be a physician licensed to practice medicine in Georgia, and be certified in anatomic pathology by the American Board of Pathology, or the American Osteopathic Board of Pathology, and be licensed by the Department as a laboratory director.

(v) A cytotechnologist general supervisor must meet the requirements of Rule 290-9-8-4(b) 6(iii) and have 3 years full time experience as a cytotechnologist in a clinical laboratory.

(vi) A histocompatibility supervisor must be a pathologist who is board certified in anatomical and clinical pathology, a licensed physician or doctor of osteopathy with four years experience in histocompatibility, or a Ph.D. with two years general immunology and two years histocompatibility experience.

(vii) The histopathology supervisor must be a licensed physician or doctor of osteopathy, and be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology, and licensed by the Department as a laboratory director.

(viii) The histotechnologist general supervisor must have formal training, be certified by an approved crediting agency and have two years of pertinent experience.

6. Persons who have been continuously engaged as laboratory supervisors in Georgia since July 1, 1970, are exempt from the personnel qualifications listed above. Persons who initially qualified under this provision and who become inactive for two (2) consecutive years for any reason must meet current requirements. Provided, further, individuals and laboratories so concerned must meet all other standards of performance required by this law and applicable rules and regulations.

(4) **Technologist.**

(a) **Responsibilities and general requirements.** Technologists, under general supervision, exercise independent judgment to perform and report findings proficiently for clinical laboratory tests. In the case of technologists who are qualified only in limited

laboratory specialties, work as a technologist shall be limited to those respective specialties in which qualified.

(b) **Qualifications.** Each technologist shall successfully complete a certification examination from the American Society for Clinical Pathology (ASCP), the American Medical Technologists (AMT), the National Credentialing Agency for Laboratory Personnel (NCA), the American Association of Bioanalysts (AAB), or another agency approved by the Department, and shall meet one of the following requirements, listed in 1 through 7 below:

1. Successful completion of a full course of study which meets all academic requirements for a bachelor's degree in medical technology from an accredited college or university; or

2. Successful completion of three years of academic study (a minimum of 135 quarter hours or equivalent) in an accredited college or university and the successful completion of a course of training of at least 12 months in a school of medical technology accredited by an agency recognized by the Council for Higher Education Accreditation (CHEA) or the U. S. Department of Education; or

3. Successful completion in an accredited college or university of a course of study which meets all academic requirements for a bachelor's degree in one of the chemical, physical, or biological sciences, and have at least one year of pertinent laboratory experience or training accepted by the Department; or

4. Successful completion of 135 quarter hours in an accredited college or university, including 24 quarter hours of chemistry, 24 quarter hours of biology, and 5 quarter hours of mathematics, (thirty quarter hours of the total, with a minimum of fifteen in science, must be at the third or fourth year level), and have at least two years of pertinent laboratory experience; or

5. Successful completion of a full course of study which meets all academic requirements for an associate's degree in medical technology from an accredited college or university, or successful completion of two years of academic study (a minimum of 90 quarter hours or equivalent) in an accredited college or university which included at least 20 quarter hours of lecture and laboratory courses in chemical, physical, or biological sciences acceptable toward a major in science, with at least three years of pertinent laboratory experience; or graduation from high school and successful completion of a formal technician training course which is accredited by an accrediting agency accepted by the Department with at least four years of pertinent laboratory experience; or

6. In the limited specialty laboratory or limited laboratory specialty(ies), a technologist is restricted to the category or subcategory of testing authorized to be performed in the limited laboratory, and must have satisfactorily completed either:

(i) Ninety (90) quarter hours in an accredited college or university with at least 20 quarter hours in science and one year of pertinent laboratory experience or training accepted by the Department; or

(ii) At least two years of pertinent laboratory experience as a technician under the supervision of a director qualified in the specialty, or a one-year formal training program accepted by the Department in the specialty; or

(iii) Cytotechnologists must be certified by specialty examination by the American Society for Clinical Pathology (ASCP), or another agency approved by the Department; or

(iv) Histotechnologists must have formal training and specialty certification by the American Society for Clinical Pathology (ASCP) or another agency acceptable to the Department.

7. Persons who possess the technologist qualifications under provisions (b) 1 through 6 above and have recently moved into the state or have recently completed the academic and training/experience requirements may be temporarily classified once as technologists for eighteen (18) months to afford the persons an opportunity to successfully complete an approved qualifying examination.

8. Persons who have been continuously engaged as technologists in Georgia since July 1, 1970, are exempt from the personnel qualifications listed above. Persons who initially qualified under this provision but become inactive for two consecutive years must meet current requirements. Provided, further, that individuals and laboratories so concerned must meet all other standards of performance required by this law and applicable rules and regulations.

(c) **Technologist allowable testing.** Technologists shall be permitted to independently perform all laboratory procedures for which the technologist has been trained and demonstrated competency as described under 290-9-8-.06(2)(a)1(i). Where the technologist chooses to delegate the performance of any test requiring more than limited skill and responsibility and exercise of independent judgment as described in 290-9-8-.06(5)(c):

1. The delegating technologist shall ensure that the individual to whom the testing has been delegated meets at a minimum the qualifications described in 290-9-8-.06(5)(b) and has documented competency for performance of the test as described in 290-9-8-.06(2)(a)1(i);

2. The delegating technologist shall be responsible for the accuracy of the test results; and

3. The delegating technologist shall ensure that a qualified technologist is available on-site or by telephone for consultation regarding the testing or for review of results; and

4. In those cases where a qualified technologist is not available on site during the performance of the delegated test, but is only available on call, the performance of those tests shall only be delegated to an individual who has completed a technician-level certification test approved by the Department, has completed a full course of study which meets all academic requirements for an associate's degree in medical technology from an accredited college or university, and has completed a minimum of two years of pertinent full time laboratory experience, one year of which experience has been obtained in the laboratory where they will be performing the delegated test.

(5) **Technician**.

(a) **Responsibilities and general requirements.** The laboratory must employ a sufficient number of qualified technicians to meet the workload demands, and they must function under the direct supervision of a technologist, supervisor or director. The decision regarding the degree of supervision necessary shall be determined by consideration of the complexity of the procedure, the training and capability of the technician, and the demonstrated competency of the technician in the procedure to be performed. The determination of the degree of supervision under which the technician performs any type of laboratory testing must be documented in the technician's job description and personnel record. In the case of technicians who are qualified only in limited laboratory specialties, work as a technician shall be limited to those respective specialties in which qualified.

1. For any testing performed by a technician, there must be documentation in the technician's personnel record of training and competency testing of the technician to perform the test.

2. Documentation of the test and reporting of results must be retained, for the purpose of supervisory review, for all testing performed independently by a technician.

(b) **Qualifications.** Each technician shall successfully complete a certification examination from the American Society for Clinical Pathology (ASCP), the American Medical Technologists (AMT), the National Credentialing Agency for Laboratory Personnel (NCA), the American Association of Bioanalysts (ABB), or another agency approved by the Department and shall meet one of the following requirements listed in 1 through 4 below:

1. Has earned an associate's degree in medical laboratory technology; or successful completion of two years of academic study (a minimum of 90 quarter hours or equivalent) in an accredited college or university which included at least 20 quarter hours of lecture and laboratory courses in chemical, physical, or biological sciences acceptable toward a major in science and have at least one year of pertinent laboratory experience or training accepted by the Department; or

2. Graduation from high school and successful completion of a formal technician training course which is accredited by an accrediting agency accepted by the Department; or

3. Graduation from high school and subsequent to graduation has obtained two years of pertinent laboratory experience in a clinical laboratory of a hospital, a health department, university, or in an independent clinical laboratory; or

4. For persons who possess the technician qualifications under provisions above and have recently moved into the state or completed the academic and/or training requirements, they may be temporarily classified once as technicians for eighteen (18) months to afford them an opportunity to successfully complete an approved qualifying examination.

5. Persons who have been continuously engaged as technicians in Georgia since July 1, 1970 are exempt from personnel qualifications listed above. Persons who initially qualified under this provision but become inactive for two consecutive years for any reason must meet current requirements. Provided, further, individuals and laboratories so concerned must meet all other standards of performance required by this law and applicable rules and regulations.

(c) **Technician allowable testing.** Technicians shall be permitted to perform tests requiring limited skill and responsibility and a minimal exercise of independent judgment, and for which the technician has demonstrated competency as described in 290-9-8-.06(2)(a)1(i), to include:

1. CLIA waived tests;

2. Complete blood count (CBC) utilizing automated/semi-automated methods with internal support systems;

3. Routine chemistries utilizing automated/semi-automated methods with internal support systems; and

4. Coagulation studies utilizing automated methods.

(6) **Trainee**. A trainee is a person who is enrolled in an accredited training program, or who, in a limited laboratory specialty(ies) for which there is no accredited training program, works and trains under the direct supervision of a qualified director, supervisor, or technologist qualified in the specialty(ies), but does not report actual patient test results without prior supervisory review. A person may function as a trainee for the duration of the formal approved training program or for a maximum period of 24 months.

(7) **Specimen Collector and/or Phlebotomist.** The laboratory may employ specimen collectors, qualified by training and/or experience approved by the laboratory director, to perform, under general supervision, collection procedures requiring understanding and skills in the procurement of specimens for clinical laboratory analysis. Documentation of qualifying training and/or experience must be available in the laboratory's personnel files. The collector may also perform exempt screening and monitoring tests as outlined in Rule 290-9-8-.16 of these regulations. Phlebotomists certified by the American Society for Clinical Pathologists (ASCP), the American Medical Technologists (AMT), the National Healthcareer Association (NHA), the National Center for Competency Testing (NCCT), the American Association of Bioanalysts (ABB), or another professional credentialing organization that has been approved by the Department, may perform Point of Care Testing in accordance with these rules.

(8) **Point of Care Technician.**

(a) **Responsibilities and general requirements.** Point of Care technicians must function under the supervision of a laboratory director and/or supervisor appointed by the director. These technicians must complete all training requirements as outlined in subparagraph (b) of this rule.

(b) **Qualifications:**

1. Professional background. Point of Care technicians must have one of the following medical professional backgrounds: licensed registered nurse, certified nurse practitioner, licensed practical nurse, certified respiratory care professional, physician assistant, perfusionist, certified paramedic or certified emergency medical technician, radiologic technologist, certified cardiovascular technologist certified by a professional credentialing organization approved by the Department, medical technologist and medical technician qualified by these rules, or a phlebotomist certified by a

professional credentialing organization approved by the Department.

2. Training. The laboratory director is responsible for determining and maintaining documentation of an individual's credentials which qualify him or her to perform Point of Care Testing. The director may delegate this responsibility to a qualified supervisor. The documentation of qualifications to perform point of care testing must include the following: training, licensure, certification or other medical professional background information as well as competency certification documentation. In all cases, an individual must be trained and his or her competency verified prior to the director or supervisor allowing the individual to perform patient testing. Such training must include, at a minimum, proper specimen collection and handling, proper use of test instruments, proper storage, handling and preparation of test kits/reagents, quality control, quality assurance, remedial action and record keeping. Training must also include troubleshooting to the extent that results will not be reported when instrument or quality control problems arise.

(9) **Other Personnel.** Other personnel may be employed in the laboratory, such as aides, clerks, etc. These persons may assist laboratory technical staff in the performance of non-clinical tasks, but do not qualify as technical staff, perform technical tests or operate testing devices.

Authority O.C.G.A. Sec. 31-22-1 et seq.

290-9-8-.33 Enforcement.

(1) The administration and enforcement of these rules and regulations shall be in accordance with Chapters 5 and 22 of Title 31 of the Official Code of Georgia Annotated and Chapter 13 of Title 50 of the Official Code of Georgia Annotated and the Rules

and Regulations for Enforcement of Licensing Requirements, Chapter 290-1-6.

(2) A Clinical Laboratory and/or Clinical Laboratory Director License may be denied, revoked, suspended, limited or renewal denied for:

(a) Making false statements of material information on an application for a license or any other documents required by the Department;

(b) Permitting unauthorized persons to perform technical procedures or to issue or sign reports;

(c) Demonstrating incompetence in the performance or reporting of clinical laboratory examinations and procedures;

(d) Performing a test for or rendering a report to a person not authorized by law to receive such services;

(e) Referring a specimen for examination to a clinical laboratory in this state which has not been licensed or exempted under Chapter 22 of Title 31 of the Official Code of Georgia Annotated or, if not in this state, certified under all applicable federal law and associated rules and regulations;

(f) Making a report on clinical laboratory work actually performed in another clinical laboratory without designating the director and the name and address of the clinical laboratory in which the test was performed.

(g) Lending the use of the name of the licensed clinical laboratory or its personnel to an unlicensed clinical laboratory.

(h) Violating or aiding in the violation of any provision of Chapter 22 of Title 31 of the Official Code of Georgia Annotated,

or these rules and regulations.

(i) Violating any other provisions of law applicable to the proper operation of a clinical laboratory.

(3) Upon being notified of a conviction, plea, or first offender treatment of a licensed laboratory director involving the manufacture, distribution, trafficking, sale, or possession of a controlled substance or marijuana, the Department shall suspend or revoke the license of such individual as follows:

(a) Upon the first conviction, the licensed individual shall have his or her license to direct a clinical laboratory suspended for a period of not less than three months, provided, however, that in the case of a first conviction, plea, or first offender treatment for a misdemeanor the Department shall be authorized to impose a lesser sanction or no sanction upon the licensed individual, and

(b) Upon the second or subsequent conviction, the licensed individual shall have his or her license to direct a clinical laboratory revoked. The failure of a licensed laboratory director to notify the Department of a conviction as required in subsection C of Rule 290-9-8-.04(2) shall be considered grounds for revocation of his or her license to direct a clinical laboratory.

(c) A licensed laboratory director sanctioned under the foregoing subsections (a) or (b) may be entitled to reinstatement of his or her license to direct a clinical laboratory upon successful completion of a drug abuse treatment and education program approved by the Department.

(4) The operation or maintenance of an unlicensed clinical laboratory in violation of Chapter 22 of Title 31 of the Official Code of Georgia Annotated and these rules may be declared a nuisance, inimical to the public health, welfare, and safety. The Commissioner may bring an action for an injunction to restrain

such violation or to enjoin the future operation or maintenance of any such clinical laboratory until compliance with Chapter 22 of Title 31 of the Official Code of Georgia Annotated and these rules has been demonstrated to the satisfaction of the Department.

(5) It shall be a violation of these rules for the laboratory to permit the removal or obliteration of any posted notices of revocation, emergency suspension action, resolution, or inspection survey during the pendency of any revocation or emergency suspension action.

(6) The Department may post an official notice of the revocation or emergency suspension action on its website or share the notice of the revocation or emergency suspension action and any information pertaining thereto with any other agencies that may have an interest in the operation of the laboratory.

(7) The Department may suspend any requirements of these rules and the enforcement of any rules where the Governor of the State of Georgia has declared a public health emergency.

(8) Any person who violates any provision of Chapter 22 of Title 31 of the Official Code of Georgia Annotated or any of the rules and regulations promulgated thereto shall be guilty of a misdemeanor.

Authority O.C.G.A. Secs. 31-2-6, 31-22-1 et seq., 31-22-2, 31-22-6, 16-13-110 et seq.